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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,901	12/07/2001	Perry F. Renshaw	04843-033001 / MCL 1779.1	7202

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EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/008,901	RENSHAW ET AL.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-25 and 27-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-25 and 27-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment filed on April 22, 2004 has been entered. Claims 21-25, 27-38 are pending. Any rejection that is not addressed in this Office Aciton is obviated in view of Applicant's arguments.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 21-24, 27-28, 30-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Fishman US Patent 5,357,959.

2. Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive.

3. Applicant argues that the measurements described in Fishman are not quantitative of any particular relaxation parameter and thus Fishman does not disclose the step of calculating the value of any relaxation parameter. (see arguments at page 7).

4. Contrary to Applicant's arguments Fishman specifically recites the purpose of its methodology to "generate images and quantitative information" at col 6, lines 26-36:

> the patient, followed by stable xenon and/or stable krypton being provided to the patient so that it is present in-vivo during that part of the MRI procedure whose purpose it is to generate images and quantitative information based on the in-vivo presence and distribution of stable xenon and/or stable krypton and the effect of stable xenon and/or stable krypton on the dipole moment of nuclei of the structure it is physically combined with. The stable xenon and/or stable krypton is

In fact, at col 6, lines 55-65, Fishman goes on to states that the information obtained are further manipulated by computer software beyond simple subtraction steps to provide a data with diagnostic value comparison:

> equilibrium and/or washout phases of xenon and/or krypton being present in-vivo. Manipulation of the data produced by an MRI computer and software can include but is not limited to the subtraction of baseline MRI images taken without stable xenon and/or stable krypton in-vivo in the patient from those taken with stable xenon and/or stable krypton present in-vivo in the patient, and/or the use of regions of interest to analyze specific areas of any and all images either separately and combined through the use of the MRI computer and software to generate images and/or quantitative data that is of diagnostic and physiological value.

Accordingly, as stated previously Fishman anticipates the limitations of the instant claims because it not only measures the relaxation parameters inherently, but also positively perform such calculation of the relaxation parameters to provide diagnostic values. Therefore, Fishman's methodology is within the scope of the instant claims.

5. Claims 21-23, 27, 31-38 stand rejected under 35 U.S.C. 102(b) as being anticipated by Carter US Patent 5,258,369.

Applicant's arguments with respect to this rejection have been fully considered but are not persuasive.

Applicant argues that carter does not disclose calculating the value of any relaxation parameter.

In respone Examiner states that ss argued in the previous rejection, and as shown in Fishman, performing an MRI imaging includes the inherently steps providing measurements proton relaxation known as T1, and T2. such

measurements are then reported via the machinery's software systems into diagnostic values and images. Accordingly, such man ululation of data meets the instant requirement of calculating the relaxation parameters. Therefore, Carter's methods anticipate the limitations of the instant claims.

Claim Rejections - 35 USC § 103

6. Claims 21-25, 27-28, 30-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fishman US Patent 5,357,959.

7. Applicant argues that Examiner provided no explanation why claim 21 or dependent claims thereof are obvious in light of Fishman.

8. In response, Examiner replies that the scope of claim 21 and ~~dependnt~~ dependent claims thereof were described in paragraph 4. It has been well been established that lack of novelty is the epitome of obviousness. *In re May*, 574 F.2d. 1082, 197 USPQ 601, 607 (CCPA 1978). Here, no new grounds of rejection were presented. Claims were rejected over the same issues and same cited prior art. Therefore, Applicants were on proper notice that claims 21 and ~~dependnet~~ dependent claims thereof were also rejected under 103 (a) obviousness analysis.

9. In addition, paragraph No. 6 of the Office Action filed on November 5, 2003 attempts to differentitate the scope of claim 21 and 25 in that the scope of claim 25 has not elementally been viewed to differ in scope from claim 21, except the recitation of a "pre-treatment challenge." Essentially, claim 25 is viewed as a species of claim 21. Therefore, since claim 25 was rendered obvious, claim 21 will also follow the same rejection.

10. In response to Applicant's arguments with respect to claim 21, Examiner restates that Applicant has not properly interpreted Fishman. Since Fishman clearly manipulates its data before presentation, it would have been obvious to perform any type of calculation within the scope of the pending claims during the assessment process of T1 or T2 relaxation parameter.

11. With respect to claim 25, Applicant has argued that Fishman does not teach administration of a neurological or psychiatric treatment. (see Arguments at page 9, 2nd para.). In response, Examiner replies that contraty to Applicant's assertion, at least as early as 1999, Xenon was well described in the art to provide neurological benefits. See for example the attached US Patent 6,559,190 to Petzelt, which its parent PCT application was published in September 2000. Accordingly, Xenon possesses inherent neurological benefits. Therefore, Fishman uses a neurological treatment in his patients.

12. Finally applicants assertions on page 9 of the Arguments about the scope of claim 25 is noted, but are not found to be persusive. Applicants assert that Examiner's interepretation of claim 25 is not correct, because normal physiological activity can not fall within the scope of the limitation "administering to a subject a pre-treament challenge that alters a physical or chemical property of cell membranes in the brain of the subject."

In response, Examiner does not dispute the meaning of the terms the limitations "pre-treatment challenge" or "post-treatment challenge," Rather, its breath as it encompasses such normal physiological activity. Accordingly, it simply flows with basic logic that if normal physiological activity is not continued

or administered to a subject, the subject dies and therefore experiences an alteration of a physical or chemical property of cell membranes in the brain. Thus, the scope of the pending claims does not exclude the normal physiological activities. Further, Applicant assertion to the meaning of the term "administering" is considered, but again, Examiner views performing normal physiological activities as "a formal way" to continue the normal physical or chemical properties of cell membranes in the brain of a subject.

New Grounds of Rejection

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

13. Claims 21-25, 27-38 are directed to non-statutory subject matter, because it is viewed as a pure mathematical algorithm which is non-statutory, because it does not produce concrete, tangible and useful results.

Process claims are statutory when they either result in a physical transformation, or provide a practical application that produces a given result (see MPEP 2106-2-(b).

Claims 21-25, 27-38 are directed to a series of mathematical steps without establishing a physical transformation or providing a practical invention. Examiner takes the position that the recitation of each step do not appear to be properly linked to show a practical application. For example, the calculating steps merely amounts to a mathematical step for expressing a parameter. The step of administering a neurological or psychiatric treatment is not linked to the

calculations of a first or second value of a relaxation parameter. Moreover, the recited effects in claims 21 or 25 is merely an indication of a difference between the calculated measures. Accordingly, claims are deemded non-statutory.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 21-25, 27-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In particular, the specifications fails to enable the skilled artisan to practice the invention without undue experimentation. As held by *ex parte Forman,* 230 USPQ 546, BdPatApp & Int. and *In re Wands,* 858 F.2d 731, 8 USPQ2d 1400, 1404, Fed. Cir. 1988, provide several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation.

In the instant case, the state of the prior art concerning methods of assessing the effectiveness of neurological or psychiatric treatment requires therapeutic and behavioral monitoring of patients. Mere calculation of relaxation parameter for a selected region has not been identifying described as an absolute assessment of effectiveness of a psychiatric treatment. Therefore, the state of art for calculating relaxation parameters of brain is unpredictable.

Further, applicant has not described any specific calculation directed to the instantly claimed steps of calculating a first and second relaxation parameters. Nor is there any teaching as to configuring the type of calculations required to perform the steps of the instant claims. Therefore, one skilled artisan is left with no guidance as to the determination of the type of calculations required to practice the claims. Subsequently, undue experimentation is needed to practice all various possibilities of assessing the effectiveness of the claimed treatment.

Finally, there is no correlation between the measurements and the administrating of a neurological or psychiatric treatment to a subject. How can one of ordinary skill in the art correlate the differences in the first and second calculated relaxation parameter to the clinical effects of the neurological or psychiatric treatment. There is no direct linkage between the clinical outcome claimed and the process steps.

As a consequence of such shortcomings, one skilled in the art must perform undue experimentation to make and use the claimed invention.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action because the modified step incorporates mathematical steps. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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